

Science

Company Funding Arrangements – Hostbased Sites

Scope and Definitions

This policy applies to proposed company funding in all host-based HHMI laboratories led by an HHMI Investigator or Freeman Hrabowski Scholar (for purposes of this policy, each an "HHMI Laboratory Head"). It does not apply to laboratories and shared research facilities at HHMI's Janelia Research Campus.

Company funding includes any arrangement that would confer a financial benefit on the HHMI laboratory. This can include direct financial support from companies in the form of a no-strings attached gift, as defined below, or sponsored research funding. It can also include proposals from companies to provide equipment, services, or supplies, or significant discounts on purchases of goods or services, in exchange for access to or rights in research results. For purposes of this policy, funding from a non-profit entity that is an affiliate of a for-profit company is treated as company funding and is subject to this policy.

No-Strings-Attached Gifts

For a gift to be considered a no-strings-attached gift, the gift, taking into account the facts and circumstances associated with the gift: (i) cannot grant the company directly or indirectly any interest in or rights to use any invention, including but not limited to inventions made in the performance of activities supported by the gift; (ii) cannot provide the company directly or indirectly with preferential access to the host institution's technology licensing process; (iii) cannot provide the company directly or indirectly with access to the results of research supported by the gift except for results that the HHMI Laboratory Head has disclosed to other members of the scientific community at large, whether by presentation at seminars, informal scientific discussions or other public dissemination (e.g., posting on a website); and (iv) cannot provide the company with rights to use the project or research results for promotional purposes.

Clinical Trials

This policy does not apply to participation in a clinical trial (as that term is defined in <u>HHMI's</u> <u>Human Subjects Research- Host-based Sites policy</u>) as a principal investigator or co-investigator. Instead, HHMI Laboratory Head participation in clinical trials, including company-sponsored clinical trials, is subject to HHMI's Human Subjects Research policy. For clarification, company funding of human subjects research in HHMI laboratories that is not part of a clinical trial is considered company funding and is subject to this policy and the Human Subjects Research policy.

Policy

An HHMI host institution may accept funding from a company to support research in the laboratory of an HHMI Laboratory Head if, after review, HHMI concludes that the requirements of this policy are satisfied and, for funding other than no-strings attached gifts, signs the applicable agreement. In addition, any company funding must be consistent with the policies of, and approved by, the HHMI Laboratory Head's host institution.

HHMI Requirements

All Company Funding

Any company funding proposal must be consistent with HHMI's mission as a tax-exempt medical research organization devoted to the promotion of human knowledge within the basic sciences, and its effective application for public good. Each proposal must be reviewed by HHMI in advance, and must satisfy the applicable HHMI requirements described in this policy. HHMI may object to a proposed funding arrangement if it concludes that the arrangement would not be consistent with HHMI's mission or would not be in the best interests of HHMI.

Company funding cannot be used to provide any portion of the salary or benefits of any HHMI employee, including the HHMI Laboratory Head.

All Company Funding other than No-Strings-Attached Gifts

The terms of any arrangements that involve companies providing funding for research in an HHMI host-based laboratory, other than no-strings-attached gifts, must satisfy each of the following requirements:

- **Transparency**. The HHMI Laboratory Head must confirm that all laboratory members, including postdocs, graduate students, and technicians, have been informed of the company funded project and of research-related terms of the funding arrangement (for example, confidentiality, publication rights, ability to distribute published materials) that may affect them or their research. In addition, the host institution must have a mechanism for laboratory members to raise concerns that may arise regarding the impact of the funding arrangement on them or their research and have procedures for resolving any such concerns.
- **Conflict of Interest Analysis**. For all company funding projects, HHMI Laboratory Heads must comply with any conflict of interest requirements imposed by their host institutions; host institutions are responsible for identifying and managing any conflicts of interest in connection with the host institution's receipt of company funding to support research in an HHMI laboratory. HHMI host institutions must review company funding proposals for HHMI laboratories at their sites under the same conflict of interest policies and principles that apply to other host faculty, and any company funding arrangement for an HHMI laboratory must be consistent with the applicable host institution's, as well as HHMI's,

conflict of interest policies. In addition, the following special conflict of interest rules apply to any company funding proposal for an HHMI laboratory.

- An HHMI Laboratory Head may not receive funding from a given company if the HHMI Laboratory Head consults for that company or owns more than five percent (5%) of that company's equity. In addition, in cases where an HHMI Laboratory Head does not have a current relationship with a company (for example, through a consulting or licensing arrangement) but owns five percent (5%) or less of the company's equity and either (i) the HHMI Laboratory Head founded the company but is no longer actively consulting for it, or (ii) the company was formed around technology developed in the HHMI Laboratory Head's laboratory and the license of such technology is the source of the equity held by the Laboratory Head, HHMI will consider on a case-by-case basis whether to approve any proposal for the HHMI Laboratory Head's laboratory to receive funding from the company. HHMI will also engage in a case-by-case analysis if a company owning (directly or indirectly) a majority interest of a company described in clause (i) or (ii) of the preceding sentence proposes to fund research in the HHMI Laboratory Head's laboratory.
- Any proposal to provide company funding for research in an HHMI laboratory that constitutes an "observational study" (as that term is defined <u>HHMI's Human Subjects Research – Hostbased Sites policy</u>) must comply with the conflict of interest requirements in this company funding policy <u>and</u> with any more restrictive requirements in the Special Conflict of Interest Rules for Human Subjects Research set out in the Human Subjects Research policy.
- **Project Specific**. Except in the case of no-strings-attached gifts, company funding for research in an HHMI laboratory must be designated for a specific project. Each funding arrangement for distinct projects within a lab must be separately approved by HHMI. HHMI does not permit non-project-specific company funding (other than no-strings attached gifts) in its laboratories.
- Path to Publication of Research Results. The results of the project must be publishable on terms acceptable to the HHMI Laboratory Head and the host institution, taking into account the nature of the research, and in a manner consistent with HHMI's publication policies.
- Sharing of Published Research Materials. Any reagents or other research materials, data, and software that are integral to a publication of research results must be able to be shared with the academic research community following publication, consistent with <u>HHMI's</u> <u>Policy on Sharing Published Materials/Responsibilities of HHMI Authors</u>. Accordingly, the parties to any agreement providing funding for an HHMI laboratory must agree to make any of their materials, data and software that are integral to a publication available upon request (supplies permitting) on reasonable terms to scientists at nonprofit institutions so that others may validate the published results and extend them in new directions.
- Freedom for HHMI Laboratory Heads to Pursue Research Objectives. The agreement must allow HHMI to terminate participation in the project on reasonable notice and the HHMI Laboratory Head to work alone or with academic collaborators in the research field after the HHMI Laboratory Head's participation in the funded project concludes. Reasonable restrictions on research by the HHMI Laboratory Head in the field with other

companies, or with academic colleagues on projects funded by other companies, are permitted if also acceptable to the HHMI Laboratory Head and the host institution.

• Limitation on Scope of Rights Granted to Company Sponsor. The agreement cannot provide for assignment to the company of sole ownership of intellectual property developed in an HHMI laboratory. Any rights granted to the company sponsor in intellectual property developed by an HHMI laboratory (e.g., an option to negotiate for a license) must be limited to inventions or research results arising from the funded project and cannot include rights in research by an HHMI laboratory outside the scope of the funded project. This policy does not, however, preclude a host institution from granting rights in pre-existing intellectual property, so-called background intellectual property, to a company sponsor if such background intellectual property is used in the funded project and/or is necessary for the company to exercise the rights it is granted with respect to inventions or results arising from the funded project.

Procedures for Review and Documentation of Company Funding Proposals

Documentation and Parties

HHMI is a party to company funding agreements for HHMI laboratories (other than no-stringsattached gifts), together with the host institution and sponsor. HHMI's Office of General Counsel will coordinate the review and negotiation of such agreements with the appropriate host institution personnel to ensure the requirements of this policy are met and any standard or customary terms including, but not limited to, appropriate indemnification for HHMI, are included. The host institution is responsible for receiving and administering all approved company funding for an HHMI laboratory. HHMI Laboratory Heads cannot sign agreements for company funding arrangements as a party but may sign to indicate that they have read the agreement and acknowledge its terms.

HHMI Laboratory Heads exploring opportunities for receiving company funding to support research in their laboratory should complete the <u>Company Funding Questionnaire</u> on the <u>HHMI</u> <u>Science Portal</u>. The HHMI Laboratory Head's <u>HHMI attorney</u> and <u>scientific officer</u> will review the information and discuss the proposal with the HHMI Laboratory Head as necessary to confirm that the proposed project is consistent with HHMI's medical research mission and advances the HHMI Laboratory Head's research.

Related Procedures, Forms and Policies

- <u>Sharing Published Materials/Responsibilities of HHMI Authors</u>
- <u>Funding Arrangements with Nonprofit, Individual, and Governmental Sources-Host-based-Sites</u>
- Human Subjects Research Host-based Sites
- <u>Company Funding Questionnaire</u> on the <u>HHMI Science Portal</u>

Contact

Any questions about HHMI's Company Funding Arrangement Policy may be raised with the <u>HHMI</u> <u>attorney responsible for the site</u>.

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